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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/027,154	12/20/2001	Timothy G.J. Ehr	29985/01-028	1216

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EXAMINER

FOREMAN, JONATHAN M

ART UNIT	PAPER NUMBER
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3736

DATE MAILED: 05/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/027,154

Applicant(s)

EHR ET AL.

Examiner

Jonathan ML Foreman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 March 2006.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4,6,7,10,13,14,16,18 and 19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,4,6,7,10,13,14,16,18 and 19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1, 4, 6, 10, 13, 16 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 4,168,703 to Kenigsberg.

In regards to claims 1, 4, 6, 10, 13, 16 and 18, Kenigsberg discloses an elongated tube (22) including an opening and a closed distal end (Col. 3, lines 22 – 24), the tube being received in a tubular sheath (Col. 3, lines 18 – 20), the tubular sheath (12) having at least two spaced apart openings (20), the tube being slidable within the sheath to allow the opening of the tube to be aligned with the openings of the sheath (Col. 4, lines 57 – 64), the proximal end of the elongated tube is disposed outside of the proximal end of the sheath, the elongated tube comprises two markings (28), one of the markings being aligned with the proximal end of the tubular sheath when the opening of the elongated tube is aligned with one of the openings of the tubular sheath, the other of the markings being aligned with the proximal end of the tubular sheath when the opening of the elongated tube is aligned with the other opening of the sheath (Col. 3, lines 41 – 56), the proximal end of the elongated tube is connected to a pressure transducer (Col. 3, lines 24 - 27). The tubular sheath has an inside surface and the elongated tube has an outside surface, the elongated tube is frictionally received in the tubular sheath (Col. 3, lines 18 – 20). In order for the device to perform, fluid communication through the tubular sheath between the inside surface of the tubular

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sheath and the outside surface of the elongated tube must be prevented. Otherwise, pressure readings would not be obtainable at the multiple sheath openings (20; Col. 4, lines 56 – 65). Kenigsberg discloses the tubular sheath as preferably having an open distal end (Col. 2, line 60) and fails to disclose the distal end being closed. However, Kenigsberg teaches that elongated tube (22) as well as tubular members (32, 38) could have an open distal end or a closed distal end with an opening adjacent thereto (Col. 3, lines 22 – 24; Col. 3, line 67 – Col. 4, line 2; Col. 4, lines 15 – 19). Additionally, Kenigsberg teaches that it is desirable to keep the elongated tube (22) from extending past the distal end of sheath (Col. 3, lines 28 – 31). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the open distal end of the tubular sheath as disclosed by Kenigsberg to be a closed distal end with an opening adjacent thereto in that Kenigsberg discloses the two configurations as being equivalent and therefore interchangeable. Additionally, it would have been obvious to one having ordinary skill in the art to modify the open distal end of the tubular sheath as disclosed by Kenigsberg to be a closed distal end in order to keep the elongated tube (22) from extending past the distal end of the sheath. Furthermore, disclosed examples and preferred embodiments do not constitute a teaching away from a broader disclosure or nonpreferred embodiments. In re Susi, 440 F.2d 442, 169 USPQ 423 (CCPA 1971). In the present case, Kenigsberg discloses the distal end “preferably open”, but does not teach away from a closed distal end having an opening adjacent thereto.

3. Claims 7, 14 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent U.S. Patent No. 4,168,703 to Kenigsberg as applied to claims 1, 13 and 16 above and further in view of U.S. Patent No. 6,259,938 to Zarychta et al.

In regards to claims 7, 14 and 19, Kenigsberg fails to disclose the sheath of the pressure monitoring device comprising a radiopaque marker at a distal end thereof. However, Zarychta et al.

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discloses a pressure monitoring device having comprising a sheath having a radiopaque marker at a distal end thereof (Col. 4, lines 35 – 38). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the sheath as disclosed by Kenigsberg to include a radiopaque marker at a distal end as taught by Zarychta et al. in order to facilitate positioning of the sheath within the patient (Col. 4, lines 31 – 33).

Response to Arguments

Applicant's arguments filed 3/3/06 have been fully considered but they are not persuasive. Applicant asserts Kenigsberg fails to disclose a device for measuring blood pressure in a vascular structure including a tubular sheath sized for insertion into the vascular structure and a pressure transducer in fluid communication with a proximal end of an elongated tube so that blood from the vascular structure is communicated to the pressure transducer when the elongated tube opening is aligned with one of the tubular sheath openings, thereby to directly measure blood pressure. However, the Examiner disagrees. A recitation with respect to the manner in which an apparatus is intended to be employed does not impose any structural limitation upon the claimed apparatus that differentiates it from a prior art reference disclosing the structural limitations of the claim. *In re Pearson*, 494 F.2d 1399, 181 USPQ 641 (CCPA 1947); *In re Yanush*, 477 F.2d 958, 177 USPQ705 (CCPA 1973); *In re Finsterwalder*, 436 F.2d 1028, 168 USPQ 530 (CCPA 1971); *In re Casey*, 370 F.2d 576, 152 USPQ 235 (CCPA 1967); *In re Otto*, 312 F.2d 937, 136 USPQ 458 (CCPA 1963); *Ex parte Masham*, 2 USPQ2d 1647 (BbPatApp & Inter 1987). In the present case, measuring blood pressure is merely an intended use that the device as disclosed by Kenigsberg is fully capable of performing. If inserted into a blood vessel, the pressure transducer as disclosed by Kenigsberg would be in fluid communication with blood, and thus would monitor the blood pressure. The fact that Kenigsberg teaches the pressure transducer in communication with a fluid (i.e. water) that fills and exits the

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device is evidence that blood located within a vessel would be in fluid communication with the transducer if the device were introduced into a vessel. The structure of the present invention as claimed is disclosed or obvious over the disclosure of Kenigsberg.

Conclusion

4. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jonathan ML Foreman whose telephone number is (571)272-4724. The examiner can normally be reached on Monday - Friday 8:00 am - 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571)272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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